Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, and Applicants reserve the right to prosecute the subject matter of such claims in continuation and/or divisional applications.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

Specification informalities and claim objections

The specification has been amended to correct certain identified informalities. Similarly, claims 3 and 7 have been amended to remove unnecessary punctuation. In addition, claims 1 and 18 have been amended to use the more common transitory phrase "comprising." The amendments to claims 1, 3, 7 and 18 are not for purposes of patentablity, nor are they intended to change the scope of the claims in any way whatsoever.

Rejections under 35 U.S.C. §112, second paragraph

Claim 4 has been rejected under 35 U.S.C. §112, second paragraph, for lack of antecedent basis for the phrase "pharmaceutical mousse composition." Claim 4 has been amended to recite "pharmaceutical aerosol foam composition," for which proper antecedent basis exists in base claim 1.

Claim 5 has been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite in the use of the term "long chain acid." Applicants respectfully disagree. The subject term is well known and has a well accepted meaning in the art, such that one skilled in the art would be reasonably apprised of the scope of the claimed invention.

Claim 6 has been rejected under 35 U.S.C. §112, second paragraph, for use of the term "includes." Specifically, the Examiner considers the recitation of an occlusive agent that "includes petrolatum" to be indefinite in view of the dependency of claim 6 upon claim 5, which

recites specific occlusive agents. The claim has been amended to clarify that the recited occlusive agent of claim 6 is petrolatum.

Claim 9 has been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite in the use of the term "effective amount of emulsifier and/or surfactant." Specifically, the Examiner contends it is unclear what the emulsifier and/or surfactant component is effective for. Applicants respectfully disagree. As noted at page 5, second full paragraph, of the specification, the emulsifier component may be present in the composition in a "stabilizing amount."

Based on the above, Applicants submit claims 4-6 and 9 satisfy the requirements of 35 U.S.C. §112, second paragraph, and request the rejections as to these claims be withdrawn.

Rejections under 35 U.S.C. §102

Claims 1-6, 9-11, 16 and 18 have been rejected under 35 U.S.C. §102(b) as being anticipated by Breton et al. US 5,733,558. Applicants respectfully traverse the rejection.

As set forth in the specification, the subject invention includes, in part, the provision of an aerosol foam or mousse composition that includes a relatively low amount of occlusive agent, yet still is able to enhance topical delivery of a pharmaceutical. When applied, the occlusive agent forms an occlusive layer on the skin, resulting in a reduction in transepidermal water loss and increased skin hydration, which, in theory, increases skin permeability to effect enhanced skin penetration of a pharmaceutical. (See, e.g., pages 2-3 and 6-12.) In particular, claim 1 is directed to a pharmaceutical aerosol foam composition, the composition comprising, inter alia, a pharmaceutically active ingredient and an occlusive agent, where the occlusive agent is present "in an amount sufficient to form an occlusive layer on the skin." Claims 2-6, 9-11 and 16 depend from claim 1. Claim 18 is directed to a pharmaceutical aerosol dispenser comprising a pharmacetical aerosol foam composition having characteristics similar to those recited in claim 1.

Breton et al. on the other hand has nothing to do with aerosol foam or mousse compositions meeting the requirements of claim 1, or arguably for that matter even with aerosol foam or mousse compositions at all. Rather, Breton et al. is directed to the use of HMG-Coenzyme A-reductase inhibitors as an anti-aging agent. Exemplified formulations containing HMG-Coenzyme A-reductase inhibitors include creams, gels, and solutions. (See Examples 1-4, columns 6-8.) Breton et al. does provide a very general outline of certain kinds of known vehicles used for topical administration. For example, at column 4, lines 32-41, certain forms of compositions for topical administration are described, including solutions, dispersions, gels, and emulsions. Following this, at column 4, lines 42-44, compositions are described that "optionally may be in the form of aerosol compositions." Further on, at column 4, lines 50-55, yet another distinct passage describes compositions in the form of "protection, treatment or care creams, milks, lotions, gels, or foams." From these passages, there is no clear indication that Breton et al. even specifically teaches or suggests an aerosol foam or mousse compositions of any kind.

Further, even were Breton et al. to be so generously (and in Applicants' view erroneously) interpreted, Breton et al. still would not teach the claimed compositions. As discussed, the claimed pharmaceutical aerosol foam compositions successfully incorporate an occlusive agent into the composition, and furthermore do so at levels that are able to provide an occlusive layer on the skin in use, and thus enhance penetration of the pharmaceutical. Breton et al. makes no mention of or desirability for pharmaceutical foam compositions having such manner of occlusive agent.

Based on the foregoing, Applicants respectfully submit claims 1-6, 9-11, 16 and 18 are patentable under 35 U.S.C. §102(b) over Breton et al. and request withdrawal of the rejection.

Rejections under 35 U.S.C. §103

Claims 1-18 have been rejected as being unpatentable over Breton et al. as applied to claims 1-6, 9-11, 16 and 18 above, and further in view of Gers-Barlag et al. US 5,833,960. Applicants likewise respectfully traverse the rejection.

Gers-Barlag et al. is directed to light protection prepartions, and would appear to be more particularly directed to so-called "after-foaming" preparations, which foam after application to the skin, typically under the influence of an after-foaming agent. (See, e.g., column 1, lines 8-10; column 4, lines 34-56; column 8, line 64 through column 9, line 2.) This reference is relied upon by the Examiner for providing particular amounts of aqueous solvent or propellant, as recited in claims 13 and 17, respectively, and also for providing the particular solvent recited in claim 15.

At the outset, it is unclear how the combination of references is being applied to any of the claims other claims 13, 15 and 17, and on this basis alone Applicants submit the rejection as to the remaining claims should be withdrawn. In any event, the deficiencies of Breton et al. have been discussed in detail above, and the addition Gers-Berlag et al. in no way cures these deficiencies. The combination would still not meet the requirements of the claimed pharmaceutical aerosol foam compositions, i.e., pharmaceutical aerosol foam compositions that successfully incorporate an occlusive agent into the foam composition, and furthermore do so at levels that are able to provide an occlusive layer on the skin in use. Neither Breton et al. nor Gers Berlag et al. makes any mention of or desirability for pharmaceutical aerosol foam compositions having such manner of occlusive agent. Further, it is unclear to Applicants what motivation or suggestion would even exist for combining these references, as it is not apparent why one skilled in the art would consider combining HMG-Co-A formulations such as those described in Breton et al. with the after-foaming light protection formulations of Gers-Berlag et al.

For the above reasons, Applicants respectfully submit claims 1-18 are patentable under 35 U.S.C. §103(a) over Breton et al. in view of Gers-Berlag et al., and request withdrawal of the rejection.

New claims 19-32

New claims 19-32 have been introduced herein. Claim 19 is directed to a pharmaceutical aerosol foam composition where the occlusive agent is petrolatum and further where the petrolatum is present in amounts of up to 55%. Support for this claim is provided, e.g., at pages 4-5 of the specification. Claims 20-32 depend from claim 19, either directly or indirectly, and include additional claimed features supported throughout the specification and in the claims as originally filed.

Applicants submit these claims are likewise patentable over the cited references for reasons discussed above, and further because the cited references neither teach nor suggest a pharmaceutical aerosol foam having the particular recited occlusive agent petrolatum in the amounts specified.

CONCLUSION

Applicant has, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would further expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to

charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 468452000300.

Respectfully submitted,

Dated: December 14, 2001 By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph beginning at line 9 of page 2 has been amended as follows:

In a first aspect of the present invention there is provided a pharmaceutical aerosol foam composition including an effective amount of

a pharmaceutically active ingredient

an occlusive agent

an aqueous solvent; and

an organic cosolvent;

the pharmaceutically active ingredient being insoluble in [.] both water and the occlusive agent; the occlusive agent being present in an amount sufficient to form an occlusive layer on the skin, in use.

Paragraph beginning at line 24 of page 2 has been amended as follows:

The water-insoluble pharmaceutically active ingredient may be any suitable type. An analgesic such as capsaicin or piroxicam, antifungal such as clotrimazole or miconazole nitrate, antibacterial such as nitrofurazone or gramcidin, anaesthetic such as benzocaine or lidocaine, antiviral such as aciclovir or penciclovir, antipruritic such as crotamiton or phenol, antihistamine such as chlorpheniramine or triproldine, xanthine such as caffeine, sex hormone such as oestradiol or testosterone, anti-inflammatory agent or corticosteroid may be used. A corticosteroid is preferred. The corticosteroids may be selected from one or more of the group consisting of [,] betamethasone valerate and clobetasol propionate.

Paragraph beginning at line 22 of page 3 has been amended as follows:

The occlusive agent [utilised] <u>utilized</u> in the pharmaceutical composition according to the present invention may be any excipient or combination thereof that provides an occlusive layer

or hydration barrier to the skin. An occlusive layer or hydration barrier is a layer or barrier sufficient to result in reduction in trans epidermal water loss, which results in skin hydration. Suitable occlusive agents may be selected from one or more of the group consisting of mineral oils and greases, long chain acids, animal fats and greases, vegetable fats and greases, water insoluble polymers and the like. In a preferred embodiment the occlusive agent is petrolatum.

In the Claims:

Claims 1, 3, 4, 6, 7 and 18 have been amended as follows:

1. (Amended) A pharmaceutical aerosol foam composition [including] comprising:

an effective amount of a pharmaceutically active ingredient

an occlusive agent;

an aqueous solvent; and

an organic cosolvent

the pharmaceutically active ingredient being insoluble in both water and the occlusive agent;

the occlusive agent being present in an amount sufficient to form an occlusive layer on the skin, in use.

3. (Amended) A pharmaceutical aerosol foam composition according to Claim 2, wherein the pharmaceutically active ingredient is a corticosteroid selected from one or more of the group consisting of[,] betamethasone valerate[,] and clobetasol propionate.

4. (Amended) A pharmaceutical aerosol foam composition according to Claim 1, wherein the pharmaceutically active ingredient is present in amounts of from approximately 0.005% by weight to approximately 10% by weight, based on the total weight of the pharmaceutical aerosol foam [mousse] composition.

6. (Amended) A pharmaceutical aerosol foam composition according to Claim 5, wherein the occlusive agent is [includes] petrolatum.

7. (Amended) A pharmaceutical aerosol foam composition according to Claim 1, wherein the occlusive agent is present in an amount of approximately 55% by weight[_] or less, based on the total weight of the composition.

18. (Amended) A pharmaceutical aerosol dispenser [including] comprising:

a pharmaceutical aerosol foam composition including

an effective amount of a pharmaceutically active ingredient

an occlusive agent;

an aqueous solvent;

an organic cosolvent.

the pharmaceutically active ingredient being insoluble in both water and the occlusive agent;

the occlusive agent being present in an amount sufficient to form an occlusive layer on the skin, in use.